



## **FOR IMMEDIATE RELEASE**

February 12, 2004

### **St. Jude Medical's Silzone Heart Valve Class Action spreads to sixteen European countries: At Least 12,000 More Recipients Revealed "At Risk"- 36,000 Worldwide**

(Minneapolis, MN, February 12, 2004) A medical monitoring and restitution class action against St. Jude Medical, Inc. in Minnesota State Court (Ramsey County) was filed yesterday, February 11, 2004, on behalf of Silzone victims who are citizens of the European Economic Union (EEU) comprised of sixteen countries. This class of approximately 10,000 to 14,000 Western European patients with defective Silzone products still implanted in them rounds out the other major populations of Silzone victims across the world who are suing St. Jude for the defective toxic silver coating on St. Jude's flagship prosthetic heart valve products between 1997 and January 2000. The valve was removed from the market by St. Paul based St. Jude for safety reasons.

According to Steven E. Angstreich, an attorney with the Philadelphia, Pennsylvania law firm of Levy, Angstreich, Finney, Baldante, Rubenstein & Coren, P.C., who is serving as co-lead counsel for Shane O'Neill, a Silzone heart valve implantee says, "The evidence developed in the United States class action indicates that St. Jude used the European Countries as its human test site to determine if the valves were safe for use, indeed referring to it in one internal document as 'the Guinea pig continent of Europe.' St. Jude's corner cutting in the development of the Silzone products, its withholding of critical information and its callous attitude towards the Silzone patients," says Angstreich, "provide the reason why at an appropriate time in Mr. O'Neill's suit, an application will be to the presiding state court judge asking for permission to assert a punitive damages claim against St. Jude on behalf of the class." Much of this evidence has already been presented to the Federal Court in the American class action pending in Minneapolis, and supported the United States District Court's recent decision to deny St. Jude's attempt to have that case against it dismissed on January 5th, 2004. That record is presently under seal pursuant to a case management order.

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Similar class actions on behalf of American and Canadian Silzone implantees are pending in Minnesota Federal Court and the Superior Court of Justice in Toronto, Ontario and have already been certified to proceed as class actions against St. Jude. Recently, on January 5th, 2004, in the class action in the U.S., the court denied St. Jude's request for judgment in its favor based on FDA approval of Silzone coating for prosthetic heart valve devices. The Court's examination of the evidence against St. Jude showed there are questions that requires a trial.

This suit, filed by Shane O'Neill, the Silzone heart valve implantee who is both a citizen of Ireland and Canada, claims that the Silzone products were defective because of the toxic properties of the silver coating that St. Jude put on the valves to hopefully prevent endocarditis from occurring. Endocarditis is a very small but serious risk following valve replacement surgery. O'Neill had two Silzone valves implanted when he lived in Ireland. An initial Silzone valve was implanted in him in March of 1998. That valve had to be removed and replaced approximately nine months later, on December 23, 1998 because it had developed a paravalvular leak. Because his surgeon was unaware of the problems associated with St. Jude's Silzone coating, it was replaced with another Silzone coated valve. That second Silzone valve is still implanted in him and causes him great concern and requires, according to medical consultants, that he (as well as other current Silzone implantees) undergo enhanced medical examinations. O'Neill seeks in the suit to recover the costs of establishing court supervised trust funds to provide ongoing medical examinations and scientific research into Silzone's long-term toxic effects. The suit also seeks restitution from St. Jude for the costs of the defective valves and the medical care associated with its implant and its explantation. On an individual basis, his suit also seeks personal injury damages for himself and his wife related to the explantation surgery he underwent after his initial prosthetic valve failed.

In his class action complaint, O'Neill alleges that Silzone's silver comes off the valves' sewing cuffs at dangerous levels; that the silver coating is toxic to heart tissue; that the silver is responsible for causing serious and potentially fatal complications such as paravalvular leaks (leakage between the implanted valve and the heart tissue); improper healing of the prosthetic valve into the heart and thromboembolic events (strokes, TIA's heart attacks); and that St. Jude withheld critical information relating to its safety and efficacy from both regulatory authorities and the medical profession.

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A team of international team lawyers are collaborating to represent Mr. O'Neill and the class of EEU Silzone patients. This legal team is comprised of product liability and class action lawyers from England, Canada and the United States. In addition to Angstreich's firm, lawyers from the firms of Zimmerman Reed (Minneapolis), Kellogg & Sigelman, LLC (Washington, DC.) and Leigh Day & CO.(London, England) are involved in the prosecution of the suit.

For more information contact the law firm of Levy, Angstreich, Finney, Baldante, Rubenstein & Coren, P.C. at 800.601.1616 or on the web at [www.levyangstreich.com](http://www.levyangstreich.com).

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#### **Class Action Complaint Is Available Upon Request**

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